

# **EXHIBIT A**

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	
	)	Judge Patti B. Saris
THIS DOCUMENT RELATES TO	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc.,</i>	)	
No. 06-CV-11337-PBS	)	

**ABBOTT LABORATORIES, INC.’S SUPPLEMENTAL SUBMISSION OF EXHIBIT**

On October 11, 2007, Abbott filed a Motion to Compel Discovery Responses to Its Document Request Nos. 37 and 38 [Dkt. # 4790]. On November 20, 2007, Abbott filed an Emergency Motion to Compel the Production of Ira Burney Documents [Dkt. # 4892]. These motions, both of which remain pending, seek the production of documents that are maintained by CMS’s Office of Legislation. In resisting Abbott’s discovery requests, the Government argued, *inter alia*, that documents from CMS’s Office of Legislation were not relevant. Despite this argument, the Government has repeatedly sought information in this lawsuit related to the legislative process and continues to seek extensive information concerning Abbott’s lobbying efforts.

In support of its above-referenced motions, Abbott supplements its briefing with the attached exhibit. The exhibit is the Government’s Fourth Request for Production to Defendant Abbott, which the Government served on Abbott after the above-referenced motions were filed. In its Request, the Government seeks documents reflecting Abbott’s lobbying efforts “pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP.” *See* United States Fourth Request for Production to Def. Abbott, at 7 (Ex. 1). The Request seeks extensive information on Abbott’s lobbying

efforts, including payment information, all communications made in furtherance of lobbying services, all documents reflecting the scope of any lobbying services retained by Abbott, all fee agreements for lobbying services, and all data provided in connection with lobbying services.

*See id.* at 7-8.

Abbott submits this exhibit to draw the Court's attention to the fact that the Government is pursuing legislative material from Abbott while at the same time arguing that such material is irrelevant when sought from the Government. Abbott respectfully requests the Court consider this exhibit in its consideration of the discovery motions currently pending before the Court.

Dated: December 11, 2007

Respectfully submitted,

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# **EXHIBIT 1**

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	
AVERAGE WHOLESale PRICE	)	
LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	Hon. Patti Saris
	)	
<i>United States of America, ex rel. Ven-a-Care</i>	)	Mag. Judge Marianne B. Bowler
<i>of the Florida Keys, Inc. v. Abbott</i>	)	
<i>Laboratories, Inc. and Hospira, Inc.</i>	)	
CIVIL ACTION NO. 06-11337-PBS	)	

UNITED STATES' FOURTH REQUEST FOR PRODUCTION TO DEFENDANT ABBOTT

Pursuant to Rule 34 of the Federal Rules of Civil Procedure, Plaintiff, the United States of America, requests that the Defendant Abbott Laboratories, Inc. (hereafter "Abbott" or "Defendant") produce for inspection and copying each document listed below that is within Defendant's possession, custody or control. The United States requests that Defendant serve any objections to these requests and make the documents specified below available for inspection and copying at the Department of Justice within 30 days.

I. INSTRUCTIONS

A. Information and Documents sought by these requests shall include information and Documents within Defendant's possession, custody or control, or within the possession, custody or control of Defendant's agents, officers, employees, attorneys or investigators, or any person acting as one or more Defendant's representative or on one or more Defendant's behalf, including, but not limited to, any otherwise independent attorneys, accountants, or consultants.

Information and Documents sought by these requests includes information and Documents maintained at any local, regional, group, divisional or corporate office.

B. Whenever appropriate, the singular form of a word shall be interpreted as plural, and the masculine gender shall be deemed to include the feminine.

C. The fact that some portion of the documents responsive to these requests may already be in the custody of the United States does not excuse current physical production pursuant to these requests of any and all other documents not previously produced or seized. To the extent responsive documents have already been produced to the United States, prior to producing additional copies of those documents, please identify the previous production(s) which contained such documents and, to the extent possible, where such documents were located within those productions, by document control number. The United States will accept specific designation of responsive documents, by document control number, in lieu of actual production.

D. If the contention is made that any requested document is not subject to discovery in whole or part by reason of privilege or otherwise, identify each such document by date, author(s), addressee(s), recipient(s), title, subject matter, purpose, and present custody, and set forth the nature of the claimed privilege or other grounds for refusal to produce in a log consistent with the requirements of Fed. R. Civ. P. 26(b)(5).

E. If it is known that any requested document or any set of documents that may have contained documents was, but is no longer, in Abbott's possession, custody or control, state what disposition was made of the document and when, and state the date the documents were lost or destroyed.

F. All materials identified pursuant to these requests shall be segregated and labeled so as to identify to which requests such material responds, or as maintained in the ordinary course of business.

G. Selection of documents from files and other sources shall be performed in such a manner as to insure that the source and location of each document may be readily determined.

H. File folders and other containers in which YOU find documents responsive to these requests, and labels identifying those folders and other containers, shall be produced intact with such documents.

I. Documents attached to each other shall not be separated unless sufficient records are kept to permit reconstruction of such grouping and the separation is identified.

J. Consistent with Rule 26(e) of the Federal Rules of Civil Procedure, these requests are continuing in character. Defendant is thus required to amend its responses to these requests and to supplement its production if, at any time before trial, it learns that its prior responses and production are in some material respect incomplete or incorrect.

K. All document requests should be responded to in accordance with the Instructions and Definitions provided herein.

L. These requests are not intended to and should not be construed to limit or otherwise modify any other discovery request issued in this case.

## II. DEFINITIONS

A. As used herein, the term "Documents" is used in its broadest sense, as defined in the Federal Rules of Civil Procedure, and includes the original of each existing identical or non-identical copy or draft thereof, by whatever means made, of any writing of any kind. The term

"Documents" includes writings; records; files; correspondence; reports; memoranda; calendars; diaries; minutes; electronic messages; voicemail; E-mail; telephone message records or logs; computer and network activity logs; hard drives; backup data; removable computer storage media such as tapes, disks, and cards; printouts; document image files; Web pages; databases; spreadsheets; software; books; ledgers; journals; orders; invoices; bills; vouchers; checks; statements; worksheets; summaries; compilations; computations; charts; diagrams; graphic presentations; drawings; films; charts; digital or chemical process photographs; video, phonographic, tape, or digital recordings or transcripts thereof; drafts; jottings; and notes. Information that serves to identify, locate, or link such material, such as file inventories, file folders, indices, and metadata, is also included in this definition. (Where Documents are stored on computer programs, discs or tapes, the records to be produced shall be accompanied by all programming and other instructions necessary to their use or retrieval.)

B. As used herein, the terms "You," "Your," "Abbott," and "Defendant" refer to the Defendant named in this lawsuit; to its corporate predecessors, including all merged predecessor corporations; to any other past or present subsidiary, affiliate or d/b/a of the Defendant named in this lawsuit; to Hospira, Inc., and to all entities currently or formerly owned, operated, or managed by Defendant, and all current and former directors, officers, principals, partners, employees, agents, representatives, or other persons acting for or on behalf thereof, including, but not limited to, any otherwise independent attorney, accountant, investigator or consultant.

C. The term "affiliated" shall mean any form of business relationship, including, but not limited to, employee, director, officer, owner, agent, consultant, or contractor.



D. Words in the singular should be construed as including the plural, and plural words should be construed as including the singular.

E. The terms "accuracy," "accurate" or "accurately," when used in reference to Price Representations or sales transactions, are used with reference to whether the information is reflective of the prices generally and currently available in the marketplace by any purchasers, including but not limited to prices paid by wholesalers, pharmacies, oncology supply houses, group purchasing organizations or physicians.

F. The term "Price Representations" means any statement, assertion, representation or declaration of the price of any Pharmaceuticals, including but not limited to Average Wholesale Price, Wholesale Acquisition Cost, Wholesale Net Price, Direct Price, List Price or Suggested Net Trade.

G. The term "Pharmaceutical" means any drug or other product sold by You which requires a physician's prescription, and includes but is not limited to "biological" products such as hemophilia factors and intravenous solutions such as sodium chloride solution.

H. The term "Subject Drugs" means the brand name, trade name or generic products listed on the attached Exhibit A, and includes all variations of the products (i.e., packaging, dosage, owner/manufacturer, diluence, NDC number or otherwise) which may have been produced, sold, offered for sale or assigned an NDC number.

I. The term "Spread" is used to refer to the difference between the actual acquisition cost or purchase price of a Pharmaceutical (paid by purchasers of the Pharmaceuticals) and the price or cost set, published or arranged by the manufacturer or the reimbursement rate paid by third party payors (to purchasers of the Pharmaceuticals). Third party payors include Medicare,

Medicaid and private insurance. Thus, the Spread is the gross profit or margin actually or potentially realized by the purchasers of the Pharmaceuticals.

J. The term "AWP" means average wholesale price.

K. The term "WAC" means the wholesale acquisition cost or wholesaler acquisition cost.

L. The term "Direct Price" means the price You report, advertise, publish or cause to be published, directly or indirectly, as the "DP" or direct price for any Pharmaceutical.

M. The term "Best Price" means the price You report or otherwise disseminate as the best price for any Pharmaceutical, including the price You report for purposes of the Medicaid rebate program.

N. The term "AMP" means the price You report or otherwise disseminate as the average manufacturers price for any Pharmaceutical, including the price You report for purposes of the Medicaid rebate program.

O. Acyclovir means Acyclovir Sodium manufactured, sold or distributed by You, including but not limited to Acyclovir Sodium 500 mg 00074 4427 01 and Acyclovir Sodium 1 gm 00074 4452 01.

Relevant Time Period: Unless otherwise indicated in a specific request, the requests herein refer to documents created from January 1, 1991 through 2003 and documents relating to such period even though created before that period.

REQUEST FOR PRODUCTION

Plaintiff requests that Defendant produce the following:

1. All documents which mention, evidence or reflect the existence and availability in electronic form of any e-mails sent by or received by You from prior to 2002, including any evaluation of whether such materials are reasonably accessible, if or when they became not reasonably accessible, the cost of converting them into a reasonably accessible form, whether such materials are contained on back-up tapes, when such materials were copied to any back-up tapes, when such materials were converted, removed or deleted from any other form or format of electronic storage, whether you had a policy in place to address the storage, conversion or deletion of such materials, and whether such policies were followed or not.
2. All reports or data prepared by or sent to You by or on behalf of IMS Health which include any of Your Pharmaceuticals, including but not limited to any analysis, comments, studies, or action based on or performed on such reports or data.
3. All documents which mention, evidence or reflect any payments made by You or on Your behalf for lobbying services pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP.
4. All documents which mention, evidence or reflect communications between You and any other person or entity for lobbying services pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP, including but not limited to communications which mention, evidence or reflect the scope or nature of any services or analysis considered, contemplated, ordered or otherwise discussed by or between You and the person or entity performing such services.

5. All documents which mention, evidence or reflect the scope or nature of any lobbying services for which You retained any person or entity for services pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP.

6. All fee agreements or other contracts between You and any person or entity described in paragraphs 3, 4 and 5 above, including but not limited to the officers, directors, shareholders or other agents of any such person or entity, for services pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP.

7. All data provided or otherwise transmitted by You to any person or entity described in paragraphs 3, 4 and 5 above for services pertaining to the reimbursement of drugs by Medicare or Medicaid, AWP/government reimbursement issues or marketing a spread involving AWP.

8. All documents which mention, evidence, reflect, compare, contrast or analyze the prices of any of Your Pharmaceuticals with the prices of any competitive products.

9. All documents which mention, evidence, reflect, compare, contrast or analyze the prices or reimbursements rates of any of Your Pharmaceuticals with the prices or reimbursement rates of any competitive products in comparison to or in connection with the reimbursement rates of any state's Medicaid program, the Medicare program, or any private insurance program.

10. All documents which mention, evidence or reflect the reimbursement rates set by any Medicaid program, the Medicare program or any private health insurance plan and/or how those reimbursement rates affect the marketing or sale of any of Your products.

11. All documents, including but not limited to time sheets, which mention, evidence or reflect any time expended by you on as well as the identity of any person expending such time for any services described in paragraphs 3 -11 above.

12. All documents which mention, evidence or reflect the identity of any person(s) who approved any change in price for any of Your Pharmaceuticals.

13. All documents which mention, evidence or reflect any presentation prepared, delivered, revised by or presented by Virginia Tobiason regarding drug reimbursement, including but not limited to any presentation to Ross division employees in 2002 or 20003, and any presentations given in Puerto Rico.

14. All data prepared, reviewed by or sent to GeriMed by Dennis Walker.

15. All data containing regarding your Pharmaceuticals prepared, reviewed by or sent to any customer by Dennis Walker.

16. All documents which mention, evidence of reflect Abbott's gathering, or tracking of Medicare or Medicaid reimbursement rates.

17. All documents which mention, evidence or reflect whether You ever identified any violation of any corporate rule or policy regarding permissible marketing practices, including, but not limited to, the violation of any policy or procedure pertaining to marketing the spread.

18. All documents which mention, evidence or reflect whether any action, reprimand or other negative consequence resulted from any violation described in paragraph 17.

19. All Documents reflecting all sales prices for Acyclovir to all classes of trade.

20. All Documents concerning the calculation or accounting of net sales of Acyclovir.
21. All Documents which reflect all sales of Acyclovir at List Price or Direct Price.
22. All transactional data, including sales data, specifically reflecting, with respect to

Acyclovir:

- a. the date and time thereof;
- b. the name and address of the person or entity billed for the sale (the "bill-to customer") and documentation identifying the parent company, if the database or any Documents identify a subsidiary, corporate affiliate, division, satellite office or warehouse;
- c. the name and address of the person or entity to whom shipped (the "ship-to customer") and the full name and address of the parent company, if the database or Documents identify a subsidiary, corporate affiliate, division, satellite office, or warehouse;
- d. each unique field reflecting any discounts, rebates, chargebacks, returns and other price and quantity adjustments;
- e. all customer names and respective customer classification designations (a/k/a class of trade designations); and
- f. each unique field reflecting any amount paid by the customers, in total and in dollars per unit. This request includes each transaction price (and applicable per package size) and each extended amount field reflecting the amount billed to credited to or paid by the customer;
- g. each unique key field linkage to the source of each transaction price, which could be a contract number or a price list or price type designation used to identify or verify the appropriate price applicable to this transaction with this customer;
- h. each unique field of data related to a rebate to the customer that affected the price of the transaction, whether given in the ordinary course of the contract under which the transaction was conducted or under other terms or arrangements;
- i. each unique field of data related to any other contract prices applicable to the customer that affected the price of the transaction, whether given in the course of the contract under which the transaction was conducted or under other terms or arrangements;
- j. each unique field of data related to any other discount, concession, chargeback or other item of value to the customer that affected the ultimate price per unit sold in the transaction, whether given in the ordinary course of the contract under which the transaction was conducted or under other terms or arrangements;
- k. each unique inventory control number for the transaction, including each invoice number, each debit/credit memo number, and each line number for each transaction;
- l. NDC number;
- m. each applicable J-Code (Level II HCPCS);
- n. each Abbott and Hospira product number and product description;

- o. number of packages tied to this transaction;
- p. package size;
- q. extended unit type (e.g., bottle, vial, capsule or tablet);
- r. each unique field specifying information about the transaction type (such as sales, returns, adjustments, chargebacks, rebates, etc.); and
- s. any other unique field of data You consider necessary to calculate net sales price per package for each given transaction, net of all rebates, chargebacks, discounts or other adjustments.

23. Documents which reflect or relate to the prices charged for and other terms and/or conditions of sale for Acyclovir, including but not limited to pricing communication or contracting correspondence manuals, price lists, guidelines, matrices, policies, mark-up policies, mark-up formulas, formulas and/or any other pricing procedures, for each product line, and/or product, and for each customer, and /or customer group purchasing organization (GPO), and/or price reporting service, and/or class of trade or subgroup thereof or other Documents that are sufficient to identify:

- a. payment terms;
- b. discounts, rebates, chargebacks and /or other adjustments offered to any purchaser and/or class of trade;
- c. prices and terms of sale for wholesale purchasers;
- d. prices and/or discounts and/or rebates and/or other adjustments for chain pharmacy purchasers;
- e. prices and/or discounts and/or rebates and/or other adjustments for hospital purchasers;
- f. prices and/or discounts and/or rebates and/or other adjustments for managed care purchasers;
- g. prices and/or discounts and/or rebates and/or other adjustments for mail order purchasers;
- h. prices and/or discounts and/or rebates or other adjustments for any and all other purchaser class of trade or subgroup.

24. All Documents concerning all Your Price Representations for Acyclovir including but not limited to all product catalogs and all price lists.

25. Periodic reports, summaries, or any other Documents constituting or which mention, evidence or reflect the average, mean, or median or any other summary calculations of pricing for Acyclovir.

26. Data and any Documents from which You calculated AWP, WAC, Direct Price or List Price for Acyclovir which was reported to any Price Reporting Service, together with any record containing or outlining assumptions made by You in Your calculation of such prices.

27. Documents which mention, evidence or reflect AWP, WAC, Direct Price or List Price for Acyclovir.

28. Documents related to, reflecting, or referring to any changes or adjustments to AWP, WAC, Direct Price and List Price for Acyclovir.

29. All documents relating to Your decision to lower Your WACs and/or any other prices reported or submitted for Acyclovir to the Price Publications in 2000 and/or 2001.

30. All documents relating to or otherwise reflecting communications regarding the impact of the 2001 TAP Pharmaceuticals criminal plea and civil settlement on the prices or pricing practices for Acyclovir.



Respectfully submitted,

For the United States of America,

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Dated: November 30, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' Fourth Request for Production** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Mark Lavine

Dated: November 30, 2007

## EXHIBIT A

DRUG	NDC#
Sodium Chloride Injection	74196607
Water for Injection 30 ml	00074397703
Vancomycin HCl 500 mg	00074433201
Water for Injection 10 ml	00074488710
Water for Injection 20 ml	00074488720
Sterile Water for Injection	00074488750
Sodium Chloride Injection	00074488810
Sodium Chloride Injection	00074488820
Sodium Chloride Irrigation	00074613802
Sodium Chloride Irrigation	00074613803
Sodium Chloride Irrigation	00074613822
Sterile Water for Irrigation	00074613902
Sterile Water for Irrigation	00074613903
Sterile Water for Irrigation	00074613922
Vancomycin HCl 5 gm	00074650901
Vancomycin HCl 1 gm	00074653301
Vancomycin HCL 500 mg Add-Vantage	00074653401
Vancomycin HCl 1 gm Add-Vantage	00074653501
5% Dextrose in Water 50 ml	00074710013
5% Dextrose in Water 100 ml	74710023
Sodium Chloride Injection	00074710102
Sodium Chloride 0.9% 50ml	00074710113
Sodium Chloride 0.9% 100 ml	00074710123
Dextrose Injection	00074712007
Sodium Chloride Irrigation	00074713809
Sterile Water for Irrigation	00074713909
Dextrose 5%/ Kcl/NaCl 1000 ml	00074790209
Dextrose Injection	00074792202
5% Dextrose in Water 500 ml	00074792203
5% Dextrose in Water 1000 ml	00074792209
Dextrose Injection	00074792336
Dextrose Injection	00074792337
Dextrose 5% and 0.225% NaCL Injection	00074792409
Dextrose 5% and 0.225% NaCL Injection	00074792609
5% Dextrose/ NaCl 0.9% 1000 ml	00074794109
Sodium Chloride Irrigation	00074797205
Sterile Water for Irrigation	00074797305
Sodium Chloride 0.9% 250 ml	00074798302
Sodium Chloride 0.9% 500 ml	00074798303
Sodium Chloride 0.9% 1000 ml	00074798309
Sodium Chloride Injection	00074798436
Sodium Chloride Injection	00074798437
Sodium Chloride Injection	00074798509
Water for Injection 1000 ml	00074799009
Acyclovir Sodium 500 mg Vial	00074442701
Acyclovir Sodium 1 GM Vial	00074445201